纳维盈医化科技
NEWAY SINOPHC TECH

NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Information

Item	Details
Product Name	Upadacitinib
Product Number	UP-20260228
Batch Number	UP-SH2026022801
Brand	SIGALD
CAS Number	1310726-60-3
MDL Number	N/A
Formula	$C_{17}H_{19}N_7O$
Formula Weight	337.38 g/mol
Quality Release Date	28 FEB 2026

Test Results

Test	Specification (Industry Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (Upadacitinib)	≥ 99.0%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	≤ 0.5%	0.04%	%	105℃, 2 hours
Residue on Ignition	≤ 0.1%	0.002%	%	600±25℃ Ignition Method
Heavy Metals (Pb)	≤ 2 ppm	0.01 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.005 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	≤ 0.5%	0.06%	%	High Performance Liquid Chromatography (HPLC)
Sulfate (SO_4^{2-})	≤ 0.02%	0.001%	%	Turbidimetric Method
pH Value (1% DMSO suspension,25℃)	6.5-8.5	7.2	-	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
Solubility in Dimethyl sulfoxide	Freely soluble	Complies	-	Pharmacopoeia Method
Supplier Information	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with the industrial standards for Upadacitinib and meets all specified requirements. It is qualified for use.
Issue Date:28 FEB 2026